

WE CLAIM:

1. A method of screening for or identifying an agent that modulates the onset or progression of benign prostatic hyperplasia (BPH), comprising:

- 5 (a) preparing a first gene expression profile of BPH cells or BPH-like cell population;
- (b) exposing the cells to the agent
- (c) preparing second gene expression profile of the agent exposed cells ;
and
- (d) comparing the first and second gene expression profiles.

10 2. A method of claim 1, wherein the gene expression profile comprises the expression levels for one or more genes that are differentially regulated in BPH cells compared to normal prostate cells.

15 3. A method of claim 1, wherein the agent modulates the expression levels for one or more genes in the BPH cells to levels close or similar to the expression level found in normal prostate cells .

20 4. A method of claim 1, wherein the gene expression profile comprises the expression levels in BPH cells for one or more genes in Tables 1-6.

25 5. A method of claim 1, wherein the gene expression profile comprises the expression levels in BPH cells for one or more genes in Table 5.

6. A method of any one of claims 1-5, wherein the BPH cell is selected from the group consisting of prostate cells from a BPH patient, a cell line in Table 7 and a derivative thereof.

7. A method of any one of claims 2-5, wherein the expression levels are for two or more genes.

8. A method of diagnosing the onset or progression of benign prostatic hyperplasia (BPH) in a subject comprising:

(a) detecting the expression levels of one or more genes in prostate cells from the subject that are differentially regulated compared to normal prostate cells.

9. A method of claim 8, wherein the expression levels are for one or more genes in Tables 1-6.

10. A method of claim 8, wherein the expression levels are for two or more genes in Tables 1-6.

11. A method of claim 8, wherein the expression levels are for one or more genes in Table 5.

12. A method of claim 8, wherein the expression levels are for two or more genes in Table 5.

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13. A method of differentiating benign prostatic hyperplasia (BPH) from prostate cancer in a subject comprising:

(a) detecting the expression levels of one or more genes in prostate cells from the subject that are indicative of BPH rather than prostate cancer.

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14. A method of claim 13, wherein the expression levels are for one or more genes in Tables 1-6.

15. A method of claim 13, wherein the expression levels are for two or more genes in Tables 1-6.

16. A method of claim 13, wherein the expression levels are for one or more genes
5 in Table 5.

17. A method of claim 13, wherein the expression levels are for two or more genes in Table 5.

10 18. A set of oligonucleotide probes, wherein each of the probes specifically hybridizes to a gene in Tables 1-6.

15 19. A set of oligonucleotide probes, wherein each of the probes specifically hybridizes to a gene in Table 5.

20 20. A set of oligonucleotide probes of claim 18, wherein the set specifically hybridizes to nearly all the genes in Tables 1-6.

21. A set of oligonucleotide probes of claim 18, wherein the set specifically
20 hybridizes to nearly all the genes in Table 5.

22. A set of oligonucleotide probes of any one of claims 18-21, wherein the probes are attached to a solid support.

25 23. A set of oligonucleotide probes of claim 22, wherein the solid support is selected from the group consisting of a membrane, a glass support and a silicon support.

24. A solid support onto which two or more oligonucleotide probes have been attached, wherein each of the probes specifically hybridizes to a gene in Tables 1-6.

25. A solid support of claim 24, wherein the probes specifically hybridize to
5 nearly all of the genes in Tables 1-6.

26. A solid support onto which two or more oligonucleotide probes have been attached, wherein the probes specifically hybridize to a gene in Table 5.

10 27. A solid support of claim 26, wherein the probes specifically hybridize to
nearly all of the genes in Table 5.

15 28. A solid support of any one of claims 24-27, wherein the solid support is an array comprising at least 10 different oligonucleotides in discrete locations per square centimeter.

29. A solid support of claim 28, wherein the array comprises at least 100 different oligonucleotides in discrete locations per square centimeter.

20 30. A solid support of claim 28, wherein the array comprises at least 1000 different oligonucleotides in discrete locations per square centimeter.

31. A solid support of claim 28, wherein the array comprises at least 10,000 different oligonucleotides in discrete locations per square centimeter.

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32. A computer system comprising:

(a) a database containing information identifying the expression level in benign prostatic hyperplasia (BPH) tissue or cells of a set of genes comprising at least two genes in Tables 1-6; and

(b) a user interface to view the information.

33. A computer system of claim 32, wherein the set of genes comprises at least two genes in Table 5.

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34. A computer system of claim 32, wherein the database further comprises sequence information for the genes.

35. A computer system of claim 32, wherein the database further comprises 10 information identifying the expression level for the set of genes in normal prostate tissue or cells.

36. A computer system of claim 32, wherein the database further comprises 15 information identifying the expression level of the set of genes in prostate cancer tissue or cells.

37. A computer system of claim 32, further comprising records including descriptive information from an external database, which information correlates said genes to records in the external database.

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38. A computer system of claim 37, wherein the external database is GenBank.

39. A method of using a computer system of claim 32 to present information 25 identifying the expression levels in a tissue or cells of at least one gene in Tables 1-6, comprising the step of:

(a) comparing the expression level of at least one gene in Tables 1-6 in the tissue or cells to the level of expression of the gene in the database.

40. A method of claim 39, wherein the expression levels of at least two genes are compared.

41. A method of claim 39, wherein the expression levels of at least five genes are
5 compared.

42. A method of claim 39, wherein the expression levels of at least ten genes are compared.

10 43. A method of claim 39, further comprising the step of displaying the expression levels of at least one gene in the tissue or cell sample compared to the expression level in BPH.

15 44. A method of monitoring the treatment of a patient with benign prostatic hyperplasia (BPH), comprising:

- (a) administering a pharmaceutical composition to the patient;
- (b) preparing a gene expression profile from a cell or tissue sample from the patient; and
- (c) comparing the patient gene expression profile to a gene expression profile from a normal prostate cells, or a BPH tissue or cell sample without treatment.

20 45. A method of claim 44, wherein the gene expression profile comprises the expression levels for one or more genes in Tables 1-6.

25 46. A method of claim 44, wherein the gene expression profile comprises the expression levels for one or more genes in Table 5.

47. A method of claim 45 or 46, wherein the expression levels are for two or more genes.

48. A method of any one of claims 1, 8, 12, 38 or 43, wherein the gene expression profile or gene expression level is detected by branched DNA (bDNA) method.

5 49. A computer readable storage medium storing a computer program for implementing an algorithm executing method of analyzing gene expression results; said method comprising:

- (a) converting the mean expression value for each gene to 0; and
- (b) converting the high and low expression values to 1 and -1,
10 respectively.

50. The medium of claim 49, wherein the method further comprises the step of:

- (c) clustering the converted expression values to identify sets of genes with similar expression pattern.